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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEFFREY HUBBELL,
JASON SCHENSE, ANDREAS ZISCH,
and HEIKE HALL

Appeal 2010-004497
Application 10/650,509
Technology Center 1600

Before ERIC GRIMES, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, Administrative Patent Judges.

PRATS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to a bidomain protein or peptide that contains a transglutaminase substrate domain and a polypeptide growth factor. The Examiner entered four rejections for obviousness-type double patenting.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm three of the rejections, but reverse the fourth.

STATEMENT OF THE CASE

The Specification discloses that fibrin "is a natural gel with several biomedical applications . . . includ[ing] use as a sealant for vascular graft attachment, heart valve attachment, bone positioning in fractures and tendon repair" (Spec. 1). Fibrin forms when its precursor, fibrinogen, is cleaved by a protease, such as thrombin, which is followed by self-polymerization and covalent crosslinking catalyzed by the transglutaminase enzyme Factor XIIIa (id. at 2).

Appellants' invention is directed to bidomain proteins and peptides composed of a bioactive polypeptide domain, which encodes a bioactive agent such as a growth factor, and a transglutaminase substrate domain (id. at 5). The transglutaminase domain allows transglutaminase-catalyzed covalent binding of the bioactive agent to a fibrin matrix, in turn allowing delivery of the agent in advantageous situations, such as fibrin-mediated surgical applications or wound healing (see id. at 16).

Claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35 stand rejected and appealed (App. Br. 2). Claims 1, 10, 18, and 28, the independent claims, illustrate the appealed subject matter and read as follows:

> 1. A composition comprising a matrix and a bidomain protein or peptide having an amino acid sequence that comprises a transglutaminase substrate domain and a polypeptide growth factor, wherein the protein or peptide is covalently bound to the matrix by the transglutaminase substrate domain.
>
> 10. A method of attaching a polypeptide growth factor to a matrix, comprising
>
> producing a bidomain peptide or protein comprising a growth factor and a transglutaminase substrate domain; and

exposing the matrix to a transglutaminase to covalently couple the bidomain peptide or protein to the matrix and crosslink the matrix.

18. A bidomain protein or peptide comprising a transglutaminase substrate domain and a polypeptide growth factor.

28. A matrix material for forming a gel comprising
(i) a bidomain protein or peptide comprising a transglutaminase domain and a polypeptide growth factor,
(ii) fibrinogen,
(iii) factor XIIIa, and
(iv) thrombin.

The following rejections are before us for review:

(1) Claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35, for obviousness-type double patenting over claims 1-39 of U.S. Patent No. 6,331,422 B1[1] (Ans. 4-5);[2]

(2) Claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35, for obviousness-type double patenting over claims 1-18 of U.S. Patent No. 6,607,740 B1[3] (Ans. 5);

(3) Claims 1-5, 7, 9-14,16-22, 26-30, 34, and 35, for obviousness-type double patenting over claims 14-20 of U.S. Patent No. 7,247,609 B2[4] (Ans. 5-6); and

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[1] Jeffrey A. Hubbell et al., U.S. Patent No. 6,331,422 B1 (filed April 8, 1998).
[2] Supplemental Examiner's Answer entered January 7, 2010. The Examiner issued the Supplemental Answer to address issues raised in the Reply Brief entered December 8, 2008.
[3] Jeffrey A. Hubbell et al., U.S. Patent No. 6,607,740 B1 (filed October 24, 2000).

(4) Claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35, for obviousness-type double patenting over certain claims of application serial number 10/323,046, which issued as U.S. Patent No. 7,601,685 B2[5] after the appeal was filed (see Ans. 6).

DOUBLE PATENTING – THE '422 AND '740 PATENTS

In rejecting all of the appealed claims over the claims of the '422 and '740 patents, the Examiner found that, although the conflicting sets of claims were not identical, the "generic claims [of the instant application] are encompassed by the patented claims thus rendering the instant claims obvious" (Ans. 5).

Regarding these rejections, Appellants state only that they will "submit a terminal disclaimer, without prejudice, to overcome the double patenting rejection with respect to claims 1-39 of the '422 patent[, and to claims 1-35 of the '740 patent,] when the claims are determined to be otherwise patentable" (App. Br. 9).

As Appellants point to no deficiency in the Examiner's prima facie case of obviousness-type double patenting, and we detect none, we summarily affirm the Examiner's rejections over the claims of the '422 and '740 patents.

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[4] Matthias Lütolf et al., U.S. Patent No. 7,247,609 B2 (filed December 18, 2002).

[5] Jeffrey A. Hubbell et al., U.S. Patent No. 7,601,685 B2 (filed December 17, 2002). When this appeal was filed, the Examiner had entered a provisional rejection over the copending application 10/323,046, which had not yet issued as a patent (see Final Rejection 4). As the application has since issued, we have removed the provisional status of the rejection, and consider the merits of the rejection in light of the issued claims.

DOUBLE PATENTING – THE '609 PATENT

In rejecting claims 1-5, 7, 9-14,16-22, 26-30, 34, and 35, for obviousness-type double patenting over claims 14-20 of the '609 patent, the Examiner found that "[c]laims 14-20 of the patent are a species of the instantly claimed invention and as such are encompassed by the claimed invention and thus anticipate the claimed invention" (Ans. 5).

Appellants argue, among other things, that the "Examiner has provided no reason why one of ordinary skill in the art would modify the bidomain peptide recited in claims 1-20 of the '609 patent to replace the PTH [parathyroid hormone] recited in the [patented] claims with a growth factor" as recited in the appealed claims (App. Br. 13). Thus, Appellants urge, the "present claims require a growth factor, while the claims 14-20 of the '609 patent require PTH" (Reply Br. 6).[6]

The Examiner responds that Appellants' arguments directed to "specific claim species (besides that species elected) are moot as the rejection is based on the generic claim 1 and the other claims only as they read on the generic" (Ans. 7). Moreover, the Examiner urges, "claims 14-20 [of the '609 patent] clearly anticipate the instant generic claims and as such a rejection under obviousness-type Double Patenting is required" (id. at 8).

We find that Appellants have the better position.

As stated in In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a prima facie case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a

[6] Reply Brief filed December 8, 2008.

> preponderance of evidence with due consideration to persuasiveness of argument.

The Federal Circuit has identified two steps in an obviousness-type double patenting analysis:

> First, "a court construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences." [Eli Lilly & Co. v. Barr Labs., Inc., 251 F. 3d 955, 967 (Fed. Cir. 2001)]. Second, it determines whether those differences render the claims patentably distinct. Id. "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." Id.

Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc., 518 F.3d 1353, 1363 (Fed. Cir. 2008) (emphasis added).

Thus, in the instant case, if the rejected claims are anticipated by the claims of the '609 patent, a conclusion of obviousness-type double patenting is proper. See In re Berg, 140 F. 3d 1428, 1437 (Fed. Cir. 1998) (obviousness-type double patenting rejection affirmed where generic claims were anticipated by patented claims directed to a species within the genus).

We are not persuaded, however, that the Examiner has adequately explained why claims 14-20 of the '609 patent anticipate the rejected claims. Each of the rejected independent claims recites a bidomain protein or peptide that includes a transglutaminase substrate domain and a domain which is "a polypeptide growth factor" (claims 1, 18, 28) or "a growth factor" (claim 10) (see App. Br. 24-17).

We agree that claims 14-20 of the '609 patent recite fusion proteins that contain two domains, one of which is a transglutaminase substrate domain (see '609 at col. 36, ll. 7-10 (claim 14), and at col. 36, ll. 34-37 (claim 20)). However, both allegedly conflicting independent claims of '609

specify that the active agent is PTH, that is, parathyroid hormone (id. at col. 36, ll. 6 (claim 14) and 33 (claim 20); see also id. at col. 3, ll. 10-11).

While the Examiner asserts that the claims of the '609 patent clearly anticipate the claims on appeal herein, the Examiner has provided no explanation, nor pointed to any evidence of record, to support a finding that an ordinary artisan would have considered the PTH in the '609 claims to be a growth factor. We therefore agree with Appellants that the Examiner has not established a prima facie case of anticipation sufficient to show a lack of patentable distinctness between the claims of '609 and the instantly rejected claims.

The Examiner offers the following clarification:

> On 3/21/2006, the examiner required an election of species. In response, on 5/10/2006, applicants elected the Factor XIIIa substrate domain of SEQ ID No. 15 for the transglutaminase substrate domain, parathyroid hormone (PTH) for the domain containing a bioactive factor and fibrin for the matrix, with traverse. On 8/26/2006, the examiner indicated that the elected species was free of the art (no claim contains the elected species) and pursuant to 37 CFR 1.146 the examiner rejected the generic claim 1 (and the other claims as they read on the generic). On 10/05/2007, the generic claim was finally rejected on the grounds of obviousness-type double patenting.

(Ans. 3-4.)

We are not persuaded that Appellants' response to the species election requirement is sufficient to establish anticipation. While it may be true that Appellants originally elected to prosecute claims directed to PTH as the active agent, as Appellants explain (Reply Br. 6-7), since the time of the election, the claims have been amended to eliminate reference to PTH, and

to limit the active component of the bidomain protein/peptide to "a polypeptide growth factor" (see, e.g. App. Br. 24 (claim 1)).

In sum, as the Examiner has not adequately explained why an ordinary artisan would have considered PTH to be a growth hormone, nor pointed to any evidence supporting such a finding, the Examiner has not met the burden of showing that claims 14-20 of the '609 patent anticipate the rejected claims. We are therefore constrained to reverse the Examiner's obviousness-type double patenting rejection of claims 1-5, 7, 9-14,16-22, 26-30, 34, and 35 over claims 14-20 of the '609 patent.

DOUBLE PATENTING – THE '685 PATENT

In rejecting claims 1-5, 7, 9-14, 16-22, 26-30, 34, and 35, for obviousness-type double patenting over claims that ultimately issued in the '685 patent, the Examiner found that the conflicting claims "are a species of the instantly claimed invention and as such are encompassed by the claimed invention and thus anticipate the claimed invention" (Ans. 6).

Appellants argue that common ownership is a requirement for obviousness-type double patenting rejections, and that the rejection over the '685 patent is therefore improper because the '685 patent and the instant application are not commonly owned (App. Br. 18; see also id. at 6-9).

Moreover, Appellants argue, the claims of the '685 patent require the fusion protein recited therein to have an enzymatic degradation site, whereas the claims subject to the instant rejection do not require the claimed bidomain protein/peptide to have that feature (id. at 20). Thus, Appellants urge, because the Examiner has not explained why an ordinary artisan would have modified the patented claims' fusion protein to eliminate the enzymatic

degradation site, and because doing so would change the mode of operation of the invention recited in the claims of the '685 patent, the patented claims do not render the instantly rejected claims obvious (id. at 20-21; see also Reply Br. 10-11).

Appellants did not present separate arguments with respect to any of the claims subject to this ground of rejection. We select claim 18 as representative of the rejected claims. See 37 C.F.R. § 41.37(c)(1)(vii).

Appellants' arguments do not persuade us that the Examiner erred in maintaining the obviousness-type double patenting rejection of claim 18 over the claims of '046 application, which ultimately issued as the '685 patent. As noted above, genus claims in an application are properly rejected under the doctrine of obviousness-type double patenting when they are anticipated by patented claims directed to a species falling within the genus. See In re Berg, 140 F. 3d 1428, 1437.

In the instant case, claim 18 recites "[a] bidomain protein or peptide comprising a transglutaminase substrate domain and a polypeptide growth factor." Claim 1 of the '685 patent reads as follows:

> 1. A fusion protein, comprising:
> (i) a first protein domain;
> (ii) a second protein domain; and
> (iii) an enzymatic or hydrolytic cleavage site between the first and the second domains;
> wherein the first domain is a growth factor selected from the group consisting of the platelet derived growth factor superfamily and the transforming growth factor beta (TGFβ) superfamily;
> wherein the second domain is a crosslinking Factor XIIIa substrate domain;
> wherein the enzymatic cleavage site is selected from the group consisting of proteolytic substrates and polysaccharide substrates, and

> wherein the hydrolytic cleavage site comprises a substrate with a linkage which undergoes hydrolysis by an acid or a base catalyzed reaction.

('685, col. 55, ll. 29-47.)

Thus, claim 1 of the '685 patent recites a protein that contains both of the features required by instant claim 18, a transglutaminase substrate domain (the crosslinking Factor XIIIa substrate domain) and a domain encoding a growth factor. We therefore agree with the Examiner that the claims of the '685 patent anticipate instant claim 18.

We also agree with the Examiner that, in view of the "comprising" language in instant claim 18, the '685 claims' recitation of an enzymatic cleavage site not recited in instant claim 18 does not demonstrate that the '685 claims fail to anticipate the instant claims. It is extremely well settled that "'[c]omprising' is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501 (Fed. Cir. 1997).

We acknowledge Appellants' argument that, despite the "comprising" language in the rejected claims, "one must read the claims as a whole to determine their proper scope. One cannot simply read into the claims of the present application a limitation that is not recited by the claims" (Reply Br. 11).

However, following that argument would mean that claims using the transitional term "comprising" could only be anticipated by disclosures containing the exact elements claimed, and no additional ones. We are not persuaded that that is the state of the law. See, e.g., Genentech. v. Chiron, 112 F.3d at 501.

We are also not persuaded that common ownership is a requirement for an obviousness-type double patenting rejection. As stated in MPEP § 804 ¶ I.A., "[d]ouble patenting may exist between an issued patent and an application filed by the same inventive entity, or by a different inventive entity having a common inventor, and/or by a common assignee/owner" (emphasis added).

We acknowledge Appellants' arguments (App. Br. 6-9) that PTO regulations and the MPEP explain elsewhere the possibilities and procedures in double patenting situations involving common ownership. As noted, however, the MPEP explicitly lists the presence of a common inventor as an alternative element to common ownership in the double patenting analysis.

This policy is supported by the decision in In re Van Ornum, 686 F.2d 937 (CCPA 1982), in which the Court of Customs and Patent Appeals affirmed an obviousness-type double patenting rejection over a patent with a common inventor, despite a lack of common ownership. The court reasoned there that the concern over potential harassment of an infringer by multiple assignees asserting essentially the same patented invention outweighed the applicant's inability to proffer a terminal disclaimer tying together ownership of the application and conflicting patent. Id. at 944-48.

In In re Fallaux, 564 F.3d 1313 (2009), the Court of Appeals for the Federal Circuit reaffirmed the Van Ornum rationale:

> The harassment justification for obviousness-type double patenting is particularly pertinent here because the Fallaux application and the Vogels patents are not commonly owned. If the Fallaux application and the Vogels patents were commonly owned, the terminal disclaimer filed in this case would have been effective to overcome the double patenting rejection. We note that this defect was of the applicant's creation as through

> assignment it allowed ownership of the applications to be divided among different entities.

Id. at 1319 (footnote omitted).

We note that the Fallaux court explicitly stated that its opinion "should not be read to decide or endorse the PTO's view" as to "whether a patent may be used as a reference for an obviousness-type double patenting rejection where the patent shares only a common inventor with the application, rather than an identical inventive entity or a common assignee." Id. at 1315 (citing MPEP § 804 ¶ I.A. (the same passage we quote above)).

However, given the multiple assignee harassment rationale applied in Van Ornum, and its endorsement in Fallaux, we are not persuaded that common ownership is properly considered a required element of the judicially created doctrine of obviousness-type double patenting, absent direct guidance from our reviewing court.

In sum, in the instant case it is undisputed that the '685 patent and the instant application have two common inventors, Jeffrey Hubbell and Jason Schense. As discussed above, we agree with the Examiner that the '685 patent claims anticipate representative claim 18.

We therefore affirm the Examiner's obviousness-type double patenting rejection of claim 18 over the claims of the '685 patent. Claims 1-5, 7, 9-14, 16, 17, 19-22, 26-30, 34, and 35 fall with claim 18. See 37 C.F.R. § 41.37(c)(1)(vii).

SUMMARY

We affirm the Examiner's obviousness-type double patenting rejections over claims 1-39 of U.S. Patent No. 6,331,422 B1, over claims

1-18 of U.S. Patent No. 6,607,740 B1, and over the claims of U.S. Patent No. 7,601,685 B2.

However, we reverse the Examiner's obviousness-type double patenting rejection over claims 14-20 of U.S. Patent No. 7,247,609 B2.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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